

AMENDMENTS

Amendments To The Specification

Please replace on page 11 the paragraph beginning with the sentence "In both the collapsed" with the following amended paragraph:

In both the collapsed and expanded configurations, structure 130 may have a generally cylindrical shape. Structure 130 may have a design that allows it to expand radially without any significant concomitant change in its axial length. The design [[of]] also may allow for permanent deformation, or partially or completely reversible deformation of structure 130 during its expansion. FIG. 1c schematically illustrates portions of an exemplary inner structure 130 in its expanded configuration. Structure 130 shown in FIG. 1c is similar to structures shown and described in greater detail, for example, in U.S. application No. 09/642,291. Structure 130 includes interconnected serpentine segments 131. Adjacent serpentine segments 131 are interconnected by a plurality of longitudinal struts 132. End serpentine segment 131 is connected by radial members 133 to a central hollow cylindrical ring 134. Some or all of

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a components 130-134 may, for example, be fabricated from shape memory alloys.

Please replace on page 12 the paragraph beginning with the sentence "FIG. 1b shows" with the following amended paragraph:

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FIG. 1b shows, for example, device 101 expanded to a suitable expanded size for permanent deployment in atrial appendage 100. Device 101 may be used to filter blood flowing out from atrial appendage 100. Device 101 has a membrane tube 120 in which an expanding structure 130 is placed. Membrane tube 120 has a generally cylindrical shape and may have one or both of its distal and proximal ends closed. FIG. 1b shows membrane 120 having both distal and proximal closed ends 124. The membrane tube 120 can be made of ~~biocompatible~~ biocompatible materials, such as, for example, ePTFE (e.g., Gortex®), polyester (e.g., Dacron®), PTFE (e.g., Teflon®), silicone, urethane, metal fibers, or other biocompatible polymers.

Please replace on page 13 the paragraph beginning with the sentence "The hole sizes in" with the following amended paragraph:

a³ The hole sizes in the blood-permeable material included in filter elements 125 may be chosen to be sufficiently small so that harmful-size emboli are filtered out from the blood flow between appendage 100 and atrium 105 (shown partially in FIGS. 1b and 1c). Yet the hole sizes may be chosen to be sufficiently large to provide an adequate flow conductivity for emboli-free blood to pass through device 101. Filter elements 125 may have hole sizes ranging, for example, from about 50 to about 400 microns in diameter. The distribution of the hole sizes may be suitably chosen, for example, with regard to individual circumstances, to be larger or smaller than indicated, provided such holes substantially inhibit harmful size emboli from passing therethrough. The open area of filter elements 125 is preferably at least 20% of the overall surface area of the closed ends 124, although a range of about 25-60% may be preferred.

Please replace on page 14 the paragraph beginning with the sentence "For all embodiments" with the following amended paragraph:

a⁴ For all embodiments of device 101, for example, as described above, when fully deployed, membrane tube 120 is held or retained in position in atrial appendage 100 so that

94 proximal closed end 124 extends across or covers ostium 110. After initial insertion of device 101 in atrial appendage 100, expanding structure 130 is expanded, for example, by inflating balloon 140, from its initial compact size to an expanded size. Expanding structure 130 is expanded to a suitable size to press membrane tube sides 126 directly against interior walls 100a of atrial appendage 100. The direct engagement of sides 126 with interior wall tissue 100a, caused by the outward pressing by structure 130, holds ~~device 101~~ provides a degree of resistance to the movement of device 101 within atrial appendage 100 and holds device 101 in a substantially fixed position. However, this resistance to movement at least initially during the implant procedure may be reversed to allow repositioning of device 101 if necessary or desirable. The reversal may be complete or partial corresponding to the elastic deformation characteristics of structure 130. The reversal may be accomplished, for example, by deflation of balloon 140. Later, regenerative tissue growth, for example, of endothelial or endocardial tissue, conforming to the outer surface textures of sides 126 may bind sides 126 and provide additional securement of fully deployed device 101. This tissue growth binding may, for example, involve tissue

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ingrowth into partially-open surface pores of the material of sides 126, or, for example, tissue ingrowth into holes in blood-permeable material in the case where sides 126 are made of blood-permeable material having holes. This tissue growth, in conjunction with the outward pressure provided by inner structure 130, may provide additional means of reducing flow leakage about the periphery of device 101.

Please replace on page 16 the paragraph beginning with the sentence "In further embodiments" with the following amended paragraph:

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In further embodiments of device 101, expanding inner structure 130 may be a self-expanding structure. Structure 130 may have suitable biasing means, for example, springs or other elastic components, which change the configuration of structure 130 from its as-implanted collapsed configuration to its expanding configuration after device 101 has been implanted. Self-expanding structure 130 also may, for example, have components made from shape memory alloys (e.g., Nitinol®). The shape memory alloy components may be preformed to have a shape corresponding to the expanded configuration of structure 130. The ~~performed~~ preformed components may be bent or compressed to form structure 130 in its collapsed configuration. After device

as
implantation, heating or changing temperature induces the bent or compressed [[the]] shape memory alloy components to automatically revert to their ~~performed~~ preformed shapes corresponding to the expanded configuration of structure 130. FIG. 2 shows, for example, device 101 expanded by self-expanding structure [[200]] 130 to a suitable expanded size for permanent deployment in an atrial appendage 100.

Please replace on page 18 the paragraph beginning with the sentence "Device 300 may be" with the following amended paragraph:

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Device 300 may be suitably deployed to filter blood flowing through ostium 305 by extending expandable structure 310 across ostium 305. Expandable structure [[320]] 310 may be self-expanding (e.g., like structure 130 FIG. 2). Alternatively, expandable structure 310 may include externally-initiated mechanical means for expansion (e.g., like balloon 140 FIG. 1b). FIG. 4 schematically illustrates the increase in size of device 300 as expandable structure 310 is being inflated. FIG. 4 shows device 300 increasing from an initial size a to an intermediate size b, and then to a size c. As device 300 size increases, attached anchors 330 move radially outward toward the interior walls of ostium 305. When structure 310 is sufficiently expanded, anchors

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330 engage surrounding interior wall tissue and secure device
300 in position.

Please replace on page 21 the paragraph beginning with the
sentence "In another device embodiment" with the
following amended paragraph:

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In another device embodiment, a single inflatable
structure may provide the functions of both the distal and
proximal structures described above. Such a device may have
a sufficiently short axial length so that all or almost all
of the device may fit within the ostium or ostium region of
an atrial appendage. Anterior portions of the device may be
used to cover the ostium in order to direct blood flow
between the atrial appendage and the atrial chamber through
filter elements. Attached anchors may be distributed on at
least part of the exterior surface area of posterior portions
of the device. The anchors may be pins, hooks, barbs, wires
with atraumatic bulb tips or other suitable structures for
engaging tissue. The single inflatable structure may be
self-expanding or may expand in response to externally-
initiated means. When the device is expanded the anchors
attached to its posterior portions engage the rear walls of
the ostium and/or possibly the interior walls of the neck
region of the atrial appendage close to the ostium. The

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device may be fabricated using suitable membranes or fabrics made of biocompatible materials, for example, such as those mentioned earlier. Further, the biocompatible materials may have, for example, any of the structures mentioned earlier (e.g., cellular matrix, wire mesh, etc.).
